DEPARTMENT OF HEALTH AND **HUMAN SERVICES**

Public Health Service

National Institutes of Health: National Institute of Environmental Health Sciences; Notice of a Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) on August 12–13, 2003, in the Rodbell Auditorium, Rall Building at the National Institute of Environmental Health Sciences, Research Triangle Park, NC. The meeting begins each day at 8:30 a.m.

Agenda

The meeting is being held on August 12-13, 2003 from 8:30 a.m. until adjournment and is open to the public with attendance limited only by the space available. Individuals who plan to attend are asked to register with the NTP Executive Secretary (NTP Liaison and Scientific Review Office, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709; telephone: 919-541-0530; facsimile: 919-541-0295 or wolfe@niehs.nih.gov). The names of those 11:50 a.m.—Lunch Break (on your own) registered will be given to the NIEHS Security Office in order to gain access to the campus. Persons attending who have not pre-registered may be asked to provide pertinent information about the meeting, *i.e.*, title or host of meeting before gaining access to the campus. All visitors (whether or not you are preregistered) will need to be prepared to show 2 forms of identification (ID, e.g., driver's license, government ID).

Persons needing special assistance, such as sign language interpretation or

other reasonable accommodation in order to attend, are asked to notify the NTP Executive Secretary at least seven business days in advance of the meeting (see contact information above). Plans are underway for making this meeting available for viewing on the Internet (http://www.niehs.nih.gov/external/ video.htm).

A preliminary agenda is provided below. A copy of the agenda, committee roster, and any additional information, when available, will be posted on the NTP Web site (http://ntpserver.niehs.nih.gov) or available upon request to the NTP Executive Secretary (contact information provided above). Following the meeting, summary minutes will be prepared and available through the NICEATM/ICCVAM Web site (http://iccvam.niehs.nih.gov) and upon request to the NTP Liaison and Scientific Review Office (contact information above).

Preliminary Agenda

Scientific Advisory Committee on Alternative Toxicological Methods August 12-13, 2003

Rodbell Auditorium, Rall Building, National Institute of Environmental Health Sciences (NIEHS), Research Triangle Park, NC 27709

August 12, 2003

8:30 a.m.—Call to Order and Introductions Welcome from the NIEHS Director National Toxicology Program Update Update on Activities of the NTP Center for the Evaluation of Alternative Toxicological Methods and the Interagency Coordinating Committee on the Validation of Alternative Methods

- Update on Activities of the European Centre for the Validation of Alternative Methods
- U.S. Federal Agency Efforts in Test Method Development and Validation
- **Environmental Protection Agency**
- National Center for Toxicological Research of the Food and Drug Administration

1 p.m.

- U.S. Department of Agriculture
- National Institutes of Health, Office of the Director
- National Cancer Institute
- National Institute of Environmental Health Sciences and the NTP

Public Comments 5 p.m.—Adjourn

August 13, 2003

8:30 a.m.—Introductions and Call to Order

- Application of GLPs to *In Vitro* Test Methods
- ICCVAM/ECVAM Proposal for Development of International Guidance
- ECVAM Guidelines for Good Cell Culture Practices
- Public Comments

Minimum Performance Standards for Test Methods

- MPS for In Vitro Corrosivity Methods
- Public Comments

In Vitro Endocrine Binding and Transcriptional Activation Assays: Minimum Procedural Standards and Reference Chemicals

• Public Comments

12:05 p.m.—Lunch (on your own)
1 p.m.—Overview of ILSI/HESI Work
Group's Activities on Identification
of Biomarkers of Toxicity and
Summary of First Meeting
Validation of Genetically Modified

Mouse Models
• Public Comments

2:45 p.m.—Adjourn

Public Comment Welcome

• Public input at this meeting is invited and time is set aside for the presentation of public comments on any agenda topic. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. In order to facilitate planning for this meeting, persons wishing to make an oral presentation are asked to notify the NTP Executive Secretary (contact information above) by August 4, 2003, and to provide their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any). Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less then that for preregistered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to provide a copy of their statement to the NTP Executive Secretary (contact information above) by August 4, 2003, to enable review by the SACATM and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the SACATM and NIEHS/NTP staff and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site (http://ntp-server.niehs.nih.gov).

Persons may also submit written comments in lieu of making oral comments. Written comments should be sent to the NTP Executive Secretary and should be received by August 4, 2003, to enable review by the SACATM and NIEHS/NIH prior to the meeting. Persons submitting written comments should include their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) with the document.

Background

The SACATM was chartered January 9, 2002, to fulfill section 3(d) of Public Law 106-545, the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*I*-3(d)] and is composed of scientists from the public and private sectors (Federal Register: March 13, 2002: Vol. 67, No. 49, page 11358). The SACATM provides advice to the Director of the National Institute of Environmental Health Sciences (NIEHS), the Interagency Coordinating Committee on the Validation of Alternative Toxicological Methods (ICCVAM), and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) regarding statutorily mandated duties of the ICCVAM and activities of the NICEATM. The committee's charter is posted on the Web at http://iccvam.niehs.nih.gov and is available in hard copy upon request from the NTP Executive Secretary (contact information above).

Dated: July 9, 2003.

Samuel Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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